

REMARKS

Claims 1-11, 15 and 16 were pending in the present application and were rejected on various grounds. Claims 1-4 and 9-11 are cancelled, and new claim 19 is added to more fully claim the present invention and to expedite prosecution of the present application.

A telephonic interview with the Examiner on 28 July 2008 and is made of record. Claim 5 was distinguished from the Brown reference, and the Examiner raised the possibility that upon further search such distinctions may be obvious and further that Applicant's claim of placing the hoop at the target at the smaller diameter may raise a new matter issue.

Applicant respectfully requests that the Final status of the outstanding Office Action be withdrawn.

Claims 1 - 4, 9 - 11, and 15 - 16 were rejected under 35 USC 112, first paragraph. Applicant cancels claims 1 - 4, and 9 - 11 without prejudice to expedite prosecution of the present application. Regarding claims 15 and 16, various figures and the Specification, paragraph 30 referring to "...the secondary coil 12... preformed into a tight secondary coil..." supporting a vessel, and by the Figs. 11 and 12 clearly showing beginning and ending spacing of the second coil separated by a different, middle section of a greater spacing than the adjoining beginning and ending sections. And further also regarding claim 15, the Specification paragraphs 39 and 40 recite an "open spacing" at a site which does not constitute the entire secondary coil, but a portion of the secondary coil of spacing greater than the adjoining

beginning and ending sections. Applicant therefore believes that the rejection of claims 15 - 16 under 35 USC 112, first paragraph, is overcome.

Claims 1 - 10, and 15 - 16 were rejected under 35 USC 103(a) as being unpatentable over Brown et al ('199) in view of Jones ('560). The Examiner argues that Brown discloses a hoop support and procedure for opening an artery substantially as claimed, that Brown discloses a preformed hoop stent composed of a material formed into a first coil which is in turn formed into a second coil having a memory, and is adapted to hold open the vessel and thus inherently has a diameter larger than the vessel, has openings (e.g. 62, fig. 1) that allow some blood flow therethrough, and that the claimed rounded or ball ends are provided by Jones.

Applicant cancels claims 1 - 4 and 9 - 11 without prejudice to expedite the prosecution of the present application.

In the telephonic argument for distinction of claim 5 over Brown, Applicant noted that Brown is directed to apparatus and methods entirely different from the claimed invention, wherein Brown is directed to structures and methods for treating vessel aneurysms, wherein blood flow through the sided of the apparatus into the vessel aneurysm is undesirable and to be mitigated if not eliminated (col. 1, lines 1-19, col. 2, lines 47-64, etc.). The device 10 of Fig. 1A retains embolic masses to occlude the lumen (col. 4, lines 32-33). The modulator 80 (Fig. 6A) to divert blood flow away, apparently has loop spacing smaller than [beginning and ending] anchoring elements 30. By contrast, the presently claimed

invention relates to a unique procedure for opening a partially occluded coronary artery including the disposition of a hoop having a primary and a secondary loop configured to urge the target site to a nominal opening size, not found in the cited art, alone or in combination.

Regarding concerns of potential new matter issues of placing the hoop at the target at the smaller diameter and the hoop urging the target smaller diameter to a larger nominal diameter, Applicant refers to claim 5 for "opening a coronary artery" as originally filed which does not include the requirement of balloon dilation. Applicant further refers to Specification paragraph 17 which recites that the hoop support device is "...designed to hold open these areas due to the hoop strength of the device..." and later "...that upon removal of the rod or ejected from the tube, the pre-formed secondary shape will reform or re-establish itself within the area to be supported." Neither this paragraph nor the following paragraph 18, which comprises the entirety of the Summary, necessitates the step of dilation, together with the plain understanding that 'holding open' and 'reform or re-establish itself with the area' and the recitation in the Specification paragraph 8 to the "...self expanding nature of the present invention..." work to "urge the target site unsupported aperture to said nominal opening size" as claimed. Moreover, the Background discussions of Specification paragraphs 6 and 7 note that prior dilation stents typically comprise a pattern cut tube material which limits both its minimum size and expansion ratio and that the

desired application [of the present invention] would be to have "...a very small profile for placement..." thus supporting the argument that at least one embodiment of the present invention include placement in a vessel without or even inaccessible by a dilating balloon. To fully claim the present application, Applicant adds new claim 19 which includes the step of dilating the target site. Applicant therefore believes that the rejection of claims 1 - 10, and 15 - 16 were rejected under 35 USC 103(a) as being unpatentable over Brown et al ('199) in view of Jones ('560) is overcome and that no new matter is added.

Claims 1 - 10, 9 - 10 and 15 - 16 were rejected under 35 USC 103(a) as being unpatentable over Dubrul ('115) in view of Brown ('199) and further in view of Jones ('560), wherein the Examiner argues that Dubrul discloses an expandable hoop support substantially as claimed to include a secondary coil shape but does not disclose a coil primary shape and that Brown teaches holding open vessels and primary coils, and that Dubrul's expanded hoop combined with Brown's primary shape and Jones' rounded ends provides the claimed invention.

Applicant cancels claims 1 - 4 and 9 - 11 without prejudice to expedite the prosecution of the present application.

Dubrul comprises a braided structure (col 5, lines 59 et seq.) intended to 'scaffold' (Abstract, line 2) the stenotic area which is a result of an entirely different deployment process of an entirely different structure, and Dubrul is incompatible with the addition or incorporation of any primary coil (e.g. of Brown).

Moreover, Dubrul, together with the pattern cut tube stents discussed above, illustrate the entirely different structures typically applied to stenotic area prior to the present application, wherein none of the art teaches, discloses or even suggests the claimed steps according to claim 5, of:

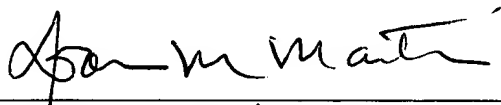
- "a. determining an artery structure nominal opening size;
- b. providing a preformed hoop composed of a primary coil of material having one of a rounded and a ball end said primary coil being wound to encircle a second axis to form a secondary coil having an outer diameter matching said nominal opening size, and instilling memory retaining properties into said preformed hoop to urge said material into said double coil;
- c. providing a cylindrical delivery means for constraining said secondary coil into a linear configuration;
- d. inserting said hoop and said delivery means into an artery at said target site having an unsupported aperture size less than said nominal opening size; and
- e. removing said delivery means whereby said hoop remains in said artery to support said artery in an open position wherein said secondary coil outer diameter is larger than said target site unsupported aperture size and said secondary coil is configured to urge said target site aperture to said nominal opening size

nor can the cited references be combined to provide the claimed process, or even combined to form any operable structure or process. The remaining claims dependent on claim 5, including new claim 19, provides further patentable features to further distinguish the present invention over the cited art of record. Applicant therefore believes that the rejection of remaining claims 5 - 8, 15 - 16 under 35 USC 103(a) as being unpatentable over Dubrul ('115) in view of Brown ('199) and further in view of Jones ('560) is overcome.

Claim 11 was rejected under 35 USC 103(a) as being unpatentable over Brown ('199) in view of Farzia-Nia ('076) and further in view of Jones ('560). Applicant cancels claim 11 without prejudice to expedite the prosecution of the present application.

Applicant, having amended the Claims, and having distinguished the present invention over the cited art of record, believes that the present application is in condition for allowance. Applicant respectfully requests that the Final status of the outstanding Office Action be withdrawn and that full reconsideration of the application and above arguments be provided, and the present application be allowed. The Examiner is invited to call the Applicant's undersigned attorney should she feel that such a call would further the prosecution of the present application.

Respectfully submitted,
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